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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/928,139	08/10/2001	Marianne Langston	GJE-136D1	6929

23557 7590 09/29/2004

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EXAMINER

CHANG, CELIA C

ART UNIT	PAPER NUMBER
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1625

DATE MAILED: 09/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/928,139

**Applicant(s)**

LANGSTON ET AL.

**Examiner**

Celia Chang

**Art Unit**

1625

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on 21 July 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-8 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### DETAILED ACTION

1. In an appeal conference it was decided that in view of the newly available references, the finality of the office action dated Dec. 19, 2003 is hereby withdrawn. The arguments presented in applicants' brief is considered as a response to the nonfinal rejection of Dec. 19, 2003.

Claims 1-8 are pending.

2. Initially, the Examiner regrets that copies of priority documents filed by applicants in the parent application was not obtained earlier. It is appreciated that additional copies were made available by applicants for evaluation.

After comparing the instant application with the two priority documents, it was noted that the priority benefit of the instant application is limited to Sept. 10, 1996 since the GB 9602174.6 application is drawn to racemization by derivatization into olifinic intermediates (not stereo isomers) instead of the instantly claimed racemization of the unwanted enantiomers.

The previous rejections of claims 1-8 and applicant's arguments with respect to them have been considered but are moot in view of the new ground(s) of rejection.

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35

U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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Claims 1-6, 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zeitline et al. US 5,733,756 or Armstrong et al. Science in view of Miller CA 94, Barry CA 119 or Miller US 4,254,261.

Determination of the scope and content of the prior art (MPEP §2141.01)

Zeitline '756 or Armstrong et al. disclosed processes for making a single enantiomer of d-threo-methylphenidate or l-threo-methylphenidate from racemic mixtures. See Zeitline '756 col. 6-7, example 5, and col. 6, example 4 wherein both acid or ester can be used to obtain the single isomer. See Armstrong's whole article with methylphenidate exemplified on page 1133 last compound of table 1.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

Zeitline or Armstrong disclosed all the elements of the claims **except** wherein a recycle by racemization step was not included. Barry taught that in preparation of amino acid esters (please note that the instant methylphenidate is a cyclic amino acid ester) analogous to the claims, racemization is achieved under acidic conditions and the analogous art by Miller (CA 94) or '261 taught that recycling the racemized isomers would give more of the intended isomer (see Miller's abstract and '261 col. 1 lines 64-66). In addition, both heat and acid were taught by the prior art as agents for racemization (see Barry and Miller).

Finding of prima facie obviousness—rational and motivation (MPEP §2142-2143)

One having ordinary skill in the art is deemed to be aware of all the pertinent art in the field. The above references placed the single enantiomer, process of making and alternative choices for increasing yield of a single isomeric form in the possession of an artisan in the field. It would have been prima facie obvious to employ a conventional modification of recycle/racemization step for the conventional process of Zeitline or Armstrong **because** producing higher yields of a desirable single isomer is expected, and such expectation is the attributes taught by the prior art. The teaching of Zeitline that either a free acid or ester can be separated suggested to one skilled in the art that a racemization step can be either before or after esterification.

Applicants argued that the importance of the instantly claimed process is that all four enantiomers existed after racemization. It is well known in the art that when compounds possess two chiral centers four enantiomers exist as its innate nature, note that Branko et al. disclosed structural delineation of the amide analog of the compound. The four enantiomers existed in mixture until stereo-separation can be made among them (see p.1714 separation by HPLC). Frigerio et al. CA 120 is hereby supplied as evidence supporting the innate nature of the four enantiomeric mixture because Frigerio et al. disclosed that they have surprisingly achieved a stereospecific synthesis wherein only two rather than the normal four was obtained. Therefore, contrary to applicants argument, the four seemed to be the "expected" results and not the other way around. Further, the Yakhotov CA 81 and Kratchanov CA 70 references provided evidence that for the specific methylphenidate, the erythro form and the threo form can only be separated with specifically designed processes of isomeric separation. Were all four not existed together, why would it be necessary to separate the threo and erythro? If it was not that all four

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enantiomers existed together, then why would it be necessary to separate the threo and the erythro form?

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zeitline et al. US 5,733,756 or Armstrong et al. Science in view of Miller CA 94, Barry CA 119 or Miller US 4,254,261 further in view of Harris US 6,242,464.

The rejection of claims 1-6 and 8 over Zeitline et al. US 5,733,756 or Armstrong et al. Science in view of Miller CA 94, Barry CA 119 or Miller US 4,254,261 is also applicable here and incorporated by reference.

The limitation of claim 7 is also conventional since the same compound and the same reagent have been used in purifying the enantiomer as claimed, see the whole article of Harris.

5. Claims 1-8 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,121,453 in view of Miller CA 94, Barry CA 119 or Miller US 4,254,261 further in view of Harris US 6,242,464.

Determination of the scope and content of the prior art (MPEP §2141.01)

Zavarch claimed a process for making a single enantiomer of d-threo-methylphenidate or l-threo-methylphenidate from racemic mixtures. See claim 1.

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Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

Zavarch claimed a similar process with all the claimed elements **except** wherein a recycle by racemization step was not included. Barry taught that in preparation of amino acid esters (please note that the instant methylphenidate is a cyclic amino acid ester) analogous to the claims, racemization is achieved under acidic conditions and the analogous art by Miller (CA 94) or '261 taught that recycling the racemized isomers would give more of the intended isomer (see Miller abstract and '261 col. 1 lines 64-66). In addition, both heat and acid were taught by the prior art as agents for racemization (see Barry and Miller).

Finding of prima facie obviousness—rational and motivation (MPEP §2142-2143)

One having ordinary skill in the art is deemed to be aware of all the pertinent art in the field. The above references placed the single enantiomer, process of making and alternative choices for increasing yield of a single isomeric form in the possession of an artisan in the field. It would have been prima facie obvious to employ a conventional modification of recycle/racemization step for the issued co-owned claim 1 of Zavarch **because** addition of a recycle/racemization step to produce higher yields of a desirable single isomer is expected, and such expectation is the attributes taught by the prior art. In the absence of unexpected results, the instant claims are an unreasonable prolonging of exclusive rights by the addition of prima facie obvious steps to the process.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

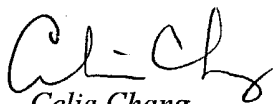
6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celia Chang whose telephone number is 571-272-0679. The examiner can normally be reached on Monday through Thursday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

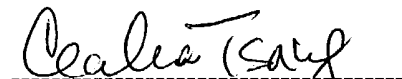
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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

OACS/Chang  
Setp. 21, 2004

  
Celia Chang  
Primary Examiner  
Art Unit 1625

Appeal conference conferee

  
Cecilia Tsang SPE 1625

  
Joseph McKane SPE 1626